New bacteria-resistant materials approved for trials on humans

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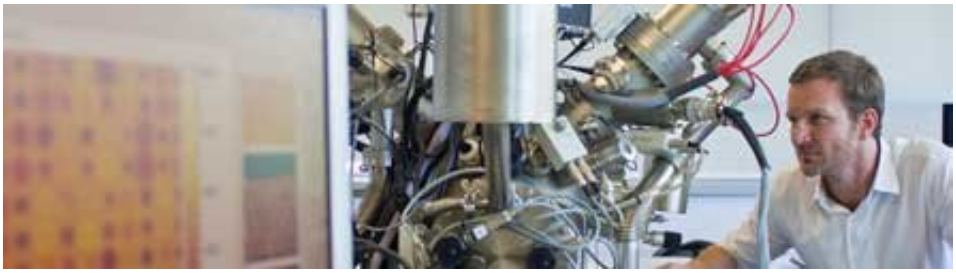

Credit: University of Nottingham

A medical device coated with new bacteria resistant materials, discovered by a team at the University of Nottingham, has been approved for use by hospitals in the UK and Europe.

The specially coated urinary catheter has just been awarded a CE mark. Devices are about to be trialled in 6 hospitals across the UK. The trial will help to determine whether promising laboratory results translate into significantly reduced infection rates and lower costs for patients needing a catheter.

The bacteria resistant materials discovered in 2012 by a scientists in the Schools of Pharmacy and Life Sciences, have been developed for medical use by the Cambridgeshire company Camstent. Meanwhile research, funded by Wellcome, to understand why these materials work is going into the final phase.

Morgan Alexander, Professor of Biomedical Surfaces, who led the team funded by a Wellcome Trust Translation Award that made the initial discovery said: "This has gone all the way from the discovery of a new class of materials that no one could have predicted all the way to clinical trials and that's a massive achievement. This is only the second medical product to ever come out of this type of high throughput materials discovery that I am aware of and although the new CE mark is for urinary catheters only we have had a lot of interest from companies who manufacture other medical devices. This is an exciting time."

Dr. Dave Hampton, Chief Technical Officer, at Camstent said: "Catheter acquired urinary tract infections account for 38% of all hospital acquired infections prolonging the time patients spend in hospital and costing many of them their lives. These infections also cost the healthcare systems around the world billions in unplanned care, increased medication and congested waiting lists. The research published by the University of Nottingham presented us with a possible solution to this problem and it's exciting to now have a product reaching clinical trial, it's a real landmark moment for the project."

Paul Williams, Professor of Molecular Microbiology in the Centre for Biomolecular Sciences said: "In the context of antimicrobial resistance these materials could be a major breakthrough. Millions of urinary catheters are used everyday around the world and anybody who has a catheter for longer than a week is likely to get an infection."

Medical device associated infections

Medical device associated infections can lead to systemic infections and device failure, costing the NHS over £1bn a year. Many commonly used devices including urinary and central venous catheters are susceptible biofilms that are essentially bacterial 'slime cities' . This lifestyle protects bacteria from the bodies' natural defences and antibiotics.

Back in 2012 the Nottingham team discovered a new group of structurally related polymers that dramatically reduced the attachment of pathogenic bacteria (including Pseudomonas, Proteus, Staphylococcus and Escherichia coli).

These new materials prevent infection by stopping biofilm formation at the earliest possible stage—when the bacteria attempt to stick irreversibly to the device.

The discovery was made with the help of experts from the Massachusetts Institute of Technology (MIT)—who initially developed the materials micro-array process by which thousands of unique polymers could be screened simultaneously.

Discovery and development

Professor Alexander said: "We do materials discovery, Camstent have done the product development. Between the point our team discovered this material and tested it on a little tube in the lab to Camstent developing a coated device there have been a host of important optimisation experiments. We needed to get the coating to the appropriate flexibility, get it to stick and then safety tested and manufactured ready for clinical trials."

The process of getting CE approval so these new materials could be tested on humans involved many well documented repetitive experiments to ensure they work and they are safe. Camstent have put them through a detailed manufacturing quality process to test the coating, packaging and sterilisation process.

Dr. Hampton said: "As well as rigorous safety tests the production process has to be tested to ensure it works and there are no faults in the manufacture and we have to ensure the devices remain sterile in the

packaging. We are very confident that we have reached a stage where patients will benefit from using this new device as opposed to the traditional uncoated or silver impregnated ones and we are very excited to see the results of these trials and move onto the next stage of the process."

Analysing the results

To test whether the materials are working properly the used catheters will be sent to the University of Nottingham where they will be examined for signs of biofilm formation by Professor Williams and his team.

Potential for other medical devices

Having licenced the materials for use in urology the team at Nottingham are now looking to use their materials on other medical devices. As well as catheters these include endotracheal tubes used to help unconscious patients breath and contact lenses. The coating could also be used for implants such as cochlear implants, prosthetic joints and dental products.

Still more questions to answer

With the discovery of new group of materials like these come big questions and Professor Morgan and his team still have some to answer.

Professor Alexander said: "We know how these materials work but the more complex question is how they work. If we can understand the mechanisms involved we can expland the application of these polymers, eg into implants and other devices. The Wellcome Trust Senior Joint Investigator award that Profs. Alexander and Williams have currently is helping us to discover why bacteria dislike our polymer surfaces so

much."

Dr. Tim Knott of Wellcome's Innovations team said: "Innovative approaches to tackling the spread of infection are vital to stop the rise of drug-resistant infections. Often called superbugs, they already kill 700.000 people each year worldwide. This new material could be hugely important in helping prevent spread of potentially deadly infection and in addressing an urgent global health problem. Reducing infection is vital for patients and for healthcare systems across the world. Wellcome is committed to tackling drug-resistant infections and we look forward to the clinical trial for this exciting medical innovation."

Provided by University of Nottingham